

AMENDMENTS TO THE CLAIMS

1. **(Currently amended)** A stable and soluble Ppharmaceutical composition characterized by comprising:
 - (a) ~~a therapeutic amount of the protease inhibitor [5S-(5R*,8R*,10R*,11R*)]-10-hydroxy-2-methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11-bis(phenylmethyl)-2,4,7,12-tetraazatridecan-13-oic acid 5-thiazolylmethyl ester (ritonavir)~~ employed in an amount ranging from 1.0% to 50% in weight of the final composition;
 - (b) a mixture of alcoholic solvent and alcoholic co-solvent from of C₂-C₄ which are employed in total amount ranging from 10% to 30% in weight of the final composition;
 - (c) a mixture of C₈-C₁₀ medium chain mono/diglycerides of C₈-C₁₀ employed in an amount ranging from 20% to 70% in weight of the final composition;
 - (d) a pharmaceutical suitable surfactant employed in an amount ranging from 0.1% to 20% in weight of the final composition;
 - (e) an antioxidant employed in an amount ranging from 0.001% to 2.0% in weight of the final composition.
2. **(Currently amended)** The Ppharmaceutical composition in accordance with claim 1, characterized by which optionally comprising further comprises:
 - (a1) an emulsion-stabilizer-stabilizing agent employed in an amount ranging up to 60% in weight of the final composition;
 - (b1) a polarity corrector agent employed in an amount up to 0.5% in weight of the final composition.
3. **(Canceled)**
4. **(Canceled)**
5. **(Canceled)**

6. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim ~~5~~ 1, characterized by wherein the alcoholic solvent is used in a concentration ranging from 5.0% to 15% in weight of the final composition.
7. (Canceled)
8. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim ~~7~~ 1, characterized by wherein the alcoholic co-solvent is used in a concentration ranging from 5.0 to 15% in weight of the final composition.
9. (Canceled)
10. (Canceled)
11. (Canceled)
12. (Canceled)
13. (Canceled)
14. (Canceled)
15. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim 1, characterized by wherein the alcoholic solvent is ethanol and the alcoholic co-solvent is propylene glycol.
16. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim 1, characterized by wherein the surfactant is polyethoxylated castor oil 35, and/or hydrogenated polyethoxylated castor oil 40, and/or polysorbates 20, 40, 60 or 80.

17. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim 1, characterized by wherein the antioxidant is butylated hydroxy toluene and/or alpha-tocopherol.

18. (Canceled)

19. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim 1 or 2, characterized by wherein the emulsion-stabilizing agent is polyethylene glycol 400 (PEG 400).

20. (Canceled)

21. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim 1 or 2, characterized by wherein the polarity corrector agent is citric acid and/or ascorbic acid.

22. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with ~~any one of~~ claims 1-21, characterized by ~~being~~ which is employed for oral administration as an oral solution, hard gelatin capsules and/or soft gelatin capsules.

23. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with claim 22, characterized by ~~being~~ which is employed for oral administration as soft gelatin capsules.

24. (Currently amended) ~~The~~ Pharmaceutical composition in accordance with ~~any one of~~ claims 1-21, characterized by ~~being~~ which is employed in the treatment of viral infections;

25. (Currently amended) ~~The~~ Pharmaceutical compositions in accordance with ~~any one of~~ claims 1-21, characterized by ~~being~~ which is employed in medicine or veterinary;

26. **(Currently amended)** Process for preparing the soluble, stable, and concentrated pharmaceutical compositions of ~~[5S-(5R*, 8R*, 10R*, 11R*)]-10-hydroxy-2-methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11-bis(phenylmethyl)-2,4,7,12-tetraazatridecan-13-oic acid-5-thiazolylmethyl ester (ritonavir),~~ of claim 1 comprising the following steps:

(a2) dissolving ~~[5S-(5R*, 8R*, 10R*, 11R*)]-10-hydroxy-2-methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11-bis(phenylmethyl)-2,4,7,12-tetraazatridecan-13-oic acid-5-thiazolylmethyl ester (ritonavir),~~ in a sufficient amount of an alcoholic solvent of C₂-C₄, under controlled temperature to make a first mixture;

(b2) eliminating solid particles from said first mixture by filtration;

(c2) evaporating the alcoholic solvent from said filtered first mixture ; under reduced pressure at low temperature to about half of its initial concentration;

(d2) adding to said filtered and concentrated first mixture an alcoholic co-solvent, a medium chain mono/diglycerides mixture, an antioxidant, an emulsion-stabilizing agent and a polarity corrector to make a second mixture in the appropriate amounts for the composition;

(e2) removing the alcoholic solvent of step (a2) from said second mixture by distilling under reduced pressure until the remaining quantity is the desired quantity in the composition;

(f2) adding to said distilled second mixture ~~the~~ a surfactant under continuous stirring, ~~and keeping stirring until said surfactant added to said distilled second complete mixture becomes a clear solution, thereby obtaining a soluble stable and concentrated ritonavir pharmaceutical composition;- and~~

(g2) correcting the ~~composition-final weight of said pharmaceutical composition~~ by adding the alcoholic solvent employed in the ~~initial dissolution of ritonavir~~ step (a2), if necessary.

27. (Currently amended) ~~The~~ Pprocess in accordance with claim 26, ~~characterized by~~ wherein the alcoholic solvent used in (a2) is ethanol.
28. (Currently amended) ~~The~~ Pprocess in accordance with claim 26, ~~characterized by~~ wherein the step (a2) is conducted in a temperature ranging from 30° C to 45°C.
29. (Currently amended) ~~The~~ Pprocess in accordance with claim 26, ~~characterized by~~ wherein the step (c2) is conducted at a maximum temperature of 40°C.
30. (Currently amended) ~~The~~ Pprocess in accordance with claim 26, ~~characterized by~~ wherein the co-solvent employed in step (d2) is propylene glycol.
31. (Currently amended) ~~The~~ Pprocess in accordance with claim 26, ~~characterized by~~ wherein the medium chain mono/diglycerides employed in step (d2) is a mixture of C₈-C₁₀ medium chain mono/diglycerides ~~of C₈-C₁₀~~.
32. (Currently amended) ~~The~~ Pprocess in accordance with claim 26, ~~characterized by~~ wherein the antioxidant employed in step (d2) is butylated hydroxy toluene or alpha-tocopherol.
33. (Currently amended) ~~The~~ Pprocess in accordance with claim 26, ~~characterized by~~ wherein the emulsion-stabilizing agent employed in step (d2) is polyethylene glycol 400 (PEG 400).
34. (Currently amended) ~~The~~ Pprocess in accordance with claim 26, ~~characterized by~~ wherein the polarity corrector is citric acid or ascorbic acid.

35. **(Currently amended)** ~~The~~ Process in accordance with claim 26, ~~characterized by~~
wherein the surfactant is polyethoxylated castor oil 35, and/or polyethoxylated hydrogenated
castor oil 40, and/or polysorbates 20, 40, 60 or 80.

36. **(Canceled)**